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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,283	09/27/2000	John A. Giordano	22920.0003	6590

23767 7590 08/13/2002

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EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/13/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Offic Action Summary	Application N .	Applicant(s)	
	09/671,283	GIORDANO ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- *The MAILING DATE of this communication appears on the c ver sheet with th corresp ndence address* --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-30 and 36-136* is/are pending in the application.

4a) Of the above claim(s) *53-116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,36-52 and 117-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment and response to the first office action of 12 March 2002, submitted May 29, 2002 (Paper No. 6) is acknowledged. Applicant's amendment is persuasive to remove the rejections under 35 USC 102 and 112.

This application contains claims 53-116 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 2-13, 39-40 and 42-52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. **Note that the recitation of intended use, regimen and/or host does not further limit a claim drawn to a composition**. The composition, regardless of the host to whom it is administered (i.e., its intended use) remains the same.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15, 18, 20-30, 36-52 and 117-120, 122-136 are rejected under 35 U.S.C. 102(e) and 102 (a) as being anticipated by Riley (USPN 5,976,568).

Riley (USPN 5,976,568) teaches an oral daily dosage composition comprising about 0.7 to about 15 mg Vitamin B-1, about 0.7 to about 15 mg vitamin B2, about 2 to 100 mg vitamin B6, about 6 to about 100 mg niacin (in form of niacinamide), about 50.0 to about 800 mcg folate (in form of folic acid), about 4 to about 50 mg pantothenic acid (in form of d-calcium pantothenate), about 0.5 to about 40 mcg vitamin B12, about 5 to about 300 mcg biotin, about 5 to about 30 mg zinc, about 10.0 to about 200 mcg selenium (in form of L-selenomethionine), about 10 to about 300 mcg chromium, about 20.0 to about 1,000 mg vitamin C (comprising ascorbic acid), about 5 to about 2000 mg vitamin E (in form of d-alpha tocopheryl succinate), see claim 1 and tables 2 and 3 in particular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-30, 36-52 and 117-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (USPN 5,976,568).

Riley (USPN 5,976,568) teaches an oral daily dosage composition comprising about 0.7 to about 15 mg Vitamin B-1, about 0.7 to about 15 mg vitamin B2, about 2 to 100 mg vitamin B6, about 6 to about 100 mg niacin (in form of niacinamide), about 50.0 to about 800 mcg folate (in form of folic acid), about 4 to about 50 mg pantothenic acid (in form of d-calcium pantothenate), about 0.5 to about 40 mcg vitamin B12, about 5 to about 300 mcg biotin, about 5 to about 30 mg zinc, about 10.0 to about 200 mcg selenium (in form of L-selenomethionine), about 10 to about 300 mcg chromium, about 20.0 to about 1,000 mg vitamin C (comprising ascorbic acid), about 5 to about 2000 mg vitamin E (in form of d-alpha tocopheryl succinate), see claim 1 and tables 2 and 3 in particular.

Riley does not particularly teach the preferred salts of zinc and chromium herein. Neither does it teach the exact ranges herein.

It would have been obvious to one of ordinary skill in the art to employ any chromium slat (e.g., picolinate or chloride) and any zinc salt (i.e., L-methionine) in the composition of Riley. The ranges herein would have also been obvious to the skilled artisan.

One of ordinary skill in the art would have been motivated to employ any chromium slat (e.g., picolinate or chloride) and any zinc salt (i.e., L-methionine) in the composition of Riley because a Skilled Artisan possessing a pharmaceutical active, also possesses the salts, acids and esters of the said active. Employing a known salt, acid, ester of a known compound in lieu of the compound itself is within the skill of the artisan. Moreover, the Skilled Artisan would expect the salts, acids, esters of a known compound to exhibit therapeutic effects similar to those of the

compound itself. Optimization of amounts is within the skill of the artisan and is therefore obvious.

Response to Arguments

Applicant's arguments with respect to the rejections under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments as to the objections in the previous office action have been fully considered but they are not persuasive. **Note that the recitation of intended use, regimen and/or host does not further limit a claim drawn to a composition**. The composition, regardless of the host to whom it is administered (i.e., its intended use) remains the same.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on July 19, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar, J.D.
Patent Examiner
August 6, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200